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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,171	01/25/2002	Thomas A. Vendola	PC11014AGLK	5278

7590 07/18/2002  
Gregg C. Benson  
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Eastern Point Road  
Groton, CT 06340

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/057,171

Applicant(s)

VENDOLA, THOMAS A.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "enhanced compressive properties" in claim 33 renders the claims indefinite because it is unclear what compressive properties are encompassed by the claims. Is it the hardness of the tablet? Or is it the compressability of the tablet? Will enhancing such properties make the tablet stronger? Or enhancing such properties will make the tablet "easier" to be compressed (e.g., like chewy tablets)?

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinemann et al. (US Patent 3,885,026 from the IDS received April 24, 2002) in view of Remington (Remington's Pharmaceutical Sciences, 18<sup>th</sup> ed., 1990, pages 1633-1647).

Heinemann et al. teaches a method of preparing a tablet by incorporating volatile solids such as camphor, ammonium bicarbonate, and menthol, into tableting components mixture; after the mixture is compressed into a tablet form, the volatile solids are removed by sublimation (See the abstract, col. 2, lines 7-16; also claims 1-2). Heinemann et al. teaches that volatile solids are employed in a weight ratio of 10-30 percent (See col. 2, lines 22-25; also claims 3-4).

Heinemann et al. does not teach the wet or dry granulation method being employed. Heinemann et al. does not teach the compression of the tablet after the volatile solids are removed. Heinemann et al. does not teach the employment of a compressive agent into the composition.

Remington teaches that wet and dry granulation method is a well-known, commonly used methods of preparation for tablets (See page 1641, col. 2 – page 1644, col. 2, last paragraph). Remington also teaches compressible sugars such as lactose, sucrose, and starch can be used for direct compression (See page 1645, col. 2, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ wet and dry granulation method and incorporate a compressive agent into the method of Heinemann et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet by further compressing the resulting composition of Heinemann et al.

One of ordinary skill in the art would have been motivated to employ wet and dry granulation method and incorporate a compressive agent into the method of Heinemann

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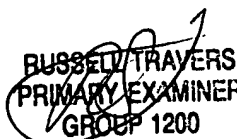
et al. because the wet and dry granulation and incorporating compressive agents are well-known in the art to be useful for formulating a tablet. Employing well-known method and excipients in formulating pharmaceutical composition would be obvious as being within the purview of skilled artisan.

One of ordinary skill in the art would have been motivated to prepare a tablet by further compressing the resulting composition of Heinemann et al. After the volatile solids are removed, the composition become porous. Because of the porous nature of the resulting composition, further compression can be applied which would be reasonably expected to make the tablet more compact and stronger thereby.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200